

K253074 Tandem Mobi insulin pump with interoperable technologyNov 6, 2025
44 days to decisionK253074 · Product code: **QFG** · Chemistry
Source: <https://www.510kdatabase.net/k253074/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alternate Controller Enabled Insulin Infusion Pump (QFG)
Date received	Sep 23, 2025
Decision date	Nov 6, 2025
Days to decision	44 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tandem Diabetes Care, Inc.
Location	San Diego, CA, US
Contact	Omar Mirza
510(k) history	25 submissions · 23 cleared · 2011-2026

Tandem Diabetes Care, Inc. is an American medical device manufacturer based in San Diego, California. The company develops medical technologies for insulin infusion therapy and diabetes treatment. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2011. Chemistry devices represent the dominant category of its regulatory portfolio. The latest FDA 510(k) clearance was granted in 2025, reflecting continued active development and regulatory engagement. Recent cleared devices include the Tandem Mobi insulin pump with interoperabl...

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